

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-358

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620

Microbiology Review #2

October 20, 1999

A. 1. ANDA: 75-358

APPLICANT: Bausch & Lomb Pharmaceuticals, Inc.
8500 Hidden River Parkway
Tampa, FL 33637

2. PRODUCT NAME: Albuterol Sulfate Inhalation Solution, 0.083% (Sterile)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Inhalation solution,
2.5 mg/3 mL, single dose unit

4. METHOD(S) OF STERILIZATION:
technology

5. PHARMACOLOGICAL CATEGORY: Bronchodilator

B. 1. DATE OF INITIAL SUBMISSION: April 14, 1998

2. DATES OF AMENDMENTS:
June 9, 1999 (Received June 10, 1999)
August 12, 1999 (Facsimile Amendment; Received August 13, 1999)
October 1, 1999 (Received October 4, 1999) – **Subject of this Review**

3. RELATED DOCUMENTS: Establishment Inspection Report (EIR)

4. ASSIGNED FOR REVIEW: 10/14/1999

C. REMARKS: Data regarding filter media validation and sterilization of the container/closure during the form/fill/seal process were reviewed by Dr. Mary Fanning during a pre-approval inspection (May 1999) and reported to be adequate in the EIR.

D. CONCLUSION: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

Paul C. DeLeo 10/20/99
Paul C. DeLeo, Ph. D.

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micro Rev 2

10/20/99

OFFICE OF GENERIC DRUGS, HFD-620

Microbiology Review #1

September 7, 1999

A. 1. ANDA: 75-358

APPLICANT: Bausch & Lomb Pharmaceuticals, Inc.
8500 Hidden River Parkway
Tampa, FL 33637

2. PRODUCT NAME: Albuterol Sulfate Inhalation Solution, 0.083% (Sterile)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Inhalation solution,
2.5 mg/3 mL, single dose unit

4. METHOD(S) OF STERILIZATION: technology

5. PHARMACOLOGICAL CATEGORY: Bronchodilator

B. 1. DATE OF INITIAL SUBMISSION: April 14, 1998
Subject of this review (Received April 15, 1998)

2. DATE OF AMENDMENT: none

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: 7/30/99

C. REMARKS:

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review.

Paul C. DeLeo 9/7/99
Paul C. DeLeo, Ph. D.

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9/14/99

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